Remarks

Claims 6-8, 10-13, 15, 26, 27, 29 and 30 are pending. Claims 6, 7, 10, 11, 15, 26, 27, 29 and 30 have been amended. Figures 1, 2 and 3 are provided on separate pages. Please enter the Figures after the Abstract as separate pages, per the suggestion in the Office Action. The specification has been amended.

Objection to the specification

Applicants have amended the specification to add priority data on page 1, to present Figures 1-3 on new pages at the end of the application after the Abstract, to delete the Figures from the text of the specification, to correct the spelling of the term "Konzentration" in Figure 3, and to correct reference to Fig. 2 so that reference is correctly made to Fig. 3 on page 6. In response to the objection to the specification as lacking headings per 37 C.F.R. 1.77(b), this section of 37 C.F.R. indicates that the specification should include the headings listed in the Office Action. Accordingly, Applicants submit that arrangement of the specification with the headings is not mandatory and therefore respectfully request the Examiner to remove this objection.

Objection to the Title

Applicants have amended the title to remedy the excessive length.

Objection to the claims

Applicants have amended the claims to correct typographical errors.

Claim Rejection – 35 U.S.C. 112, first paragraph

Applicants agree with the Examiner in that the specification is enabling for inhibition of DNA synthesis in the human cell line SZ95. However, for at least the following reasons, Applicants respectfully disagree that the specification is not enabling for the full scope of the pending claims. In particular, it is commonly known that the ectopeptidases DP IV and APN are

highly expressed on human sebocytes. To assess the effects of the inhibitors recited in the present claims on human sebaceous cell functioning, Applicants employed the SZ95 cell line as a model. In connection with this model, the Examiner's attention is courteously directed to US Patent Publication 2002/0034820. This reference discloses the SZ95 cell line and teaches that a particular value of the cell line is that it has features of non-transfected, normal and differentiated sebocytes in morphological, phenotypic and functional respects. The reference discloses that the cells can therefore be used as models for physiological, pathophysiological and pharmacological studies. The reference further discloses that it was confirmed that the immortalized sebocytes can substantially maintain the phenotype of normal sebocytes and behave like non-transfected normal human sebocytes of the face in functional respects. (See paragraph [0014]). Further still, the reference discloses that the cell line can be used for diagnostic or therapeutic uses. (See paragraph [0021]). Thus, Applicants submit that one skilled in the art at the time the present application was filed would know that the SZ95 cell line is a validated, clinically relevant model for evaluating methods for inhibiting the growth of sebaceous cells in an individual.

With respect to the contention that the specification provides very little guidance in regard to making the elected species of DP IV inhibitor for treating the conditions elected, Applicants submit that one skilled in the art would know how to make and/or obtain the DP IV inhibitors, since such inhibitors known in the art. In connection with their use, Applicants submit that the SZ95 cell line is known to be a validated and clinically relevant model, and it has been conceded in the Office Action that the method of the invention is enabled for inhibition of DNA synthesis (and therefore proliferation) of SZ95 sebocyte cells. The specification also discloses that both benign follicular hyperproliferation conditions and malign follicular hyperproliferation conditions are associated with hyperproliferation of sebocytes. In connection with this, the Examiner's attention is respectfully directed to MPEP section 2164.01(b) (How to Make the Claimed Invention), which specifies that as long as the application discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied. Accordingly, Applicants submit that the full scope of the claims is enabled pursuant to guidance provided by the MPEP. Further, Applicants submit that determining optimization of dosages and routes of administration for use in the presently claimed methods is within the purview of those skilled in the art, **provided** the skilled artisan is accorded the benefit of the instant disclosure.

Therefore, Applicants disagree that undue experimentation would be required to practice the presently claimed invention.

With respect to the contention that the method is not enabled for prevention of the recited conditions, Applicants have herewith amended the claims to delete reference to the term "prevention." Thus, it is believed this rejection is rendered moot.

Claim Rejections – 35 USC 102(e)

The claims stand rejected based on the contention that they are anticipated by U.S. Patent No. 7,229,969. In support of this contention, the Examiner asserts that Figure 2 of the instant invention is identical with Figure 13 of the '969 patent.

In response, Applicants respectfully disagree. In particular, Applicants point out that Figure 13 of U.S. Patent No. 7,229,969 is not identical to Figure 2 of the instant application and is in fact quite different. Figure 13 of the '969 patent relates to mRNA expression in HaCaT keratinocytes. Figure 2 of the instant application relates to mRNA expression of in SZ95 sebocytes. It is well known in the art that keratinocytes and sebocytes are very different cell types, and have different genesis, different structures, and different functions in the human body. Thus, the same is applicable for the respective conditions caused by proliferating sebocytes versus keratinocytes. Therefore, patients in need of therapy for one condition are distinct from those in need of therapy for the other. The '969 patent accordingly does not anticipate the present application.

Conclusion

Based on the foregoing amendments and remarks, Applicants believe the claims are now in condition for allowance. The Examiner is respectfully requested to remove the rejections and allow the application. Applicants request a three-month extension of time to file this response. Fees may be charged to Deposit Account no. 08-2442.

Respectfully submitted,

/John D. Lopinski/

By: _____
John D. Lopinski, Reg. No. 50,486

HODGSON RUSS LLP

The Guaranty Building

140 Pearl Street, Suite 100

Buffalo, NY 14202-4040

Tel. 716-848-1628

Dated: October 17, 2008